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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,298	12/21/2001	Toshihiko Yanagita	YAM 2 0014	9018

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,298	YANAGITA, TOSHIHIKO	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed, 5-27-04, is hereby acknowledged. Claims 1-15 were amended and claims 16-17 were cancelled. Claims 1-15 are pending in this application.

2. All rejections made in the previous office action are hereby withdrawn. New Grounds for rejections follow below.

Claim Objections

3. Claims 8-10 are objected to because of the following informalities: The claims have a period after the letters in the subparts. The MPEP states that each claims begins with a Capital letter and end with a period and periods may not be used elsewhere in the claims except abbreviations.

There should be a space between the and adrenomedullin in claim 8.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-10 recite, independently, (c.), (d.) etc.... It is unclear from each claim if there are additional subparts. For example, claim 8 recites sub-part (c.) and (d.), it is unclear how parts (a.) and (b.) are incorporated into the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yallampalli et al. (WO9734922).

The claims are drawn to method of preventing premature labor or miscarriage using a composition comprising adrenomedullin.

The reference teaches the prevention of preterm labor using adernomedullin peptide. The reference discloses that to a human female with signs and symptoms of preeclampsia or eclampsia of pregnancy or preterm/premature labor, 0.1-0.5 nmol/kg/24 hr doses of CGRP or CGRP/adrenomedullin peptide or receptor-based analogues should be administered in equivalent doses with or without supplementation with a progestin, a NO substrate or donor (see paragraph bridging page 2-3 and 19, lines 21-56). This prevented premature or preterm labor. Note that claim 3 recites that the adernomedulillin is used to premature labor. Accordingly, both the prior art and the instant claims administer the same active agent to the same patient, a pregnant woman. Thus, the administration of adernomedullin to the pregnant woman would inherently result in a method of inhibiting spontaneous myometrial contraction or bradykinin induced contraction. In fact, the reference discloses that CGRP administration leads to an inhibition of contractions in the uterus and reduces uterine activity during pregnancy. Thus, admnistration of CGRP or

adrenomedullin would result in the treatment of spontaneous myometrial contraction or bradykinin induced contraction.

The reference further states that the method of treatment is inclusive of treating menstrual disorders such as dysmenorrhea (see page 18, lines 9-10) thus meeting the limition of claim 6.

Finally, as for the limitations of claims 4-5, it is known that a "wherein" clause that merely statest ht result of the limitation in the claim adds nothing to the patentability or substance of the claim. Here, the limitation of miscarriage and parturition, which follow the wherein clause, do not limit the claims. This is because, these are future events that result as a by product of spontaneous myometrial contraction or bradykinin induced contraction. Where adrenomedullin is used to inhibiting spontaneous myometrial contraction or bradykinin induced contraction, future events of miscarriage and parturition do not occur and thus are treated. Thus, the claimed limitations do not add anything to the patentability of the claims.

Also note that the disclosure of CGRP for the treatment of contractions and preeclampsia anticipate claims 7-10 since CGRP is a peptide that encompasses the deletion/substitution analogs claimed as the alternative embodiments in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yallampalli et al. (WO9734922) as applied to claims 1-10 above, and further in view of Kitamura et al (US5639855).

The claims are drawn to method of preventing premature labor or miscarriage using a composition comprising adrenomedullin.

The reference of Yallampalli et al. have been discussed supra. The difference the prior art and the instant application is that the reference does not disclose those sequences claimed.

However, Kitamura et al. teaches composition of adrenocdullin which is a novel hypotensive peptide that was administered to rats via intravenous injections (see col. 5, lines 42-43 and col. 13, lines 34-67). The reference also discloses that the peptide can comprise the sequence

from Ser 13 to Tyr 52, Cys 16 to Cys 21, Tyr 1 to Tyr 52, Ala-73 to Tyr 52, Met-94 to Leu 91 in the adrenoedullin peptide (see col. 1, lines 42-67 and col. 2, lines 1-10). Also, the reference discloses various substitutions, deletion, and/or additions to the peptide (see col. 2, lines 9-37). This teaching meets the limitation of claims 7-10 and 13 or the instant application. Further, the reference states that the disulfide bond or –CH2-CH2- are linked between Cys 16 and Cys 21 to crosslink the molecule (see col. 2, lines 4-10). Finally, the reference discloses that the carboxyl terminus of the N-Terminal peptide is amidated or a Gly is attached thereto (see col. 2, lines 50-55). This teaching meets the limitation of claims 11-12 of the instant application. The reference discloses that all of these modifications does not affect the activity of adrenomedullin (see abstract). Therefore it would have been obvious to use any of the analogs disclosed in Kitamura et al. because all of the peptides disclosed have activity similar to adrenomedullin and thus one would expect these analogs to be effective to prevent premature labor or miscarriage.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANISH GUPTA
PATENT EXAMINER

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